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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte DANIEL ROBERT BLAKLEY

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Appeal 2008-4553
Application 10/758,813
Technology Center 3700

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Decided: January 12, 2009

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Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims relating to electocardial waveforms. The Examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

"Typically, several electrodes are affixed to various chest locations on the patient in order to record . . . electrocardial information. Further, at least one reference electrode is placed at a location where electrical activity is minimal, such as on one of the patient's lower legs." (Spec. 1.) Such a reference electrode may "restrict[] the patient's ability to walk or even wear trousers without stressing the electrode and the skin at which the electrode is attached" (*id.*).

The Specification discloses "a reference voltage-generating circuit that supplants the reference electrode" (*id.* at 4). In particular, as depicted in Figure 4, the Specification discloses "an electrode input 45 [that] conveys an electrical voltage from one or more electrodes affixed to a patient's chest" (*id.*).

> The signal from electrode input 45 is conveyed to event detector 70. . . . [W]hen event detector 70 detects [a triggering event], timing device 80 is placed in a waiting state until the electrocardial waveform can be expected to enter an interval of relative inactivity. . . . At the onset of [an expected interval of relative inactivity], sample and hold device 85 samples the value of the input electrocardial waveform. The sampled value of the waveform is then held at the output of sample and hold device 85 and conveyed to the inverting input of [an] amplifier. The voltage sampled during the expected period of relative inactivity can then be subtracted from electrode input 45 according to the well-known subtractive transfer function of the summing amplifier of Figure 4.

(*Id.* at 4-5.)

As depicted in Figure 5, the Specification also discloses "a memory and processor replacing the event detector, timing device, and sample and hold device of Figure 4" (*id.* at 6). In particular, the Specification discloses

an "electrode input 45 [that] is input to memory 130 by way of analog to digital converter 125" (*id.*).

> [P]rocessor 140 searches for the various triggering events within the electrocardial waveform stored in memory 130. Upon the detection of an appropriate triggering event, . . . processor 140 outputs a value to reference voltage generator 145. Reference voltage generator 145 provides a voltage to the inverting input of amplifier 95. Amplifier 95 then subtracts the reference voltage from the incoming signal.

(*Id.* at 7.)

Claims 1-32 are pending and on appeal. We will focus on claims 1, 10, 16, 22, and 27, each of which is an independent claim. The dependent claims have not been argued separately and therefore each stand or fall together with the independent claim from which it depends. 37 C.F.R. § 41.37(c)(1)(vii). Independent claims 1, 10, 16, 22, and 27 read as follows:

1. A method for applying a reference value to an electrocardial waveform including a series of heart beats, the method comprising:
identifying a triggering event within the electrocardial waveform,
waiting a period of time after the triggering event for an interval of relative inactivity in the waveform;
sampling the electrocardial wavefrom during the interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and
dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat.

10. A system for generating a reference value of an electrocardial waveform including a series of beats, comprising:
at least one electrode input that conveys a voltage signal of the electrocardial waveform of a patient;
an event detector that detects an event within the electrocardial wavefrom;
a sampling device that determines the reference value corresponding to a selected beat;

a timing device that, after a wait period in response to the event detector, activates the sampling device; and

a referencing element that applies the reference value to the voltage signal over a period of the selected beat.

16. A device for recording an electrocardial waveform, comprising:

at least one input for receiving a signal from an electrode, the signal representing an electrocardial waveform;

a sampling element to digitize the received signal;

a memory element coupled to the at least on input, that stores the digitized signal;

a processor, coupled to the memory, and configured to:

identify a peak value of the received signal; and

determine a voltage value of the received signal during an interval of relative inactivity, the interval located relative to the peak value; and

a reference voltage generator for generating a voltage applied to the incoming signal substantially equal to the determined voltage value.

22. A receiver for an electrocardial signal, comprising:

digital means for characterizing an electrocardial signal, the digital means including:

a detector element for identifying at least one distinct feature of the signal;

a sampling element to determine a value for an interval of the signal; and

timing means to activate the sampling element after the feature is detected and at the start of the sampled interval; and

analog means operably coupled to the digital means for modifying the electrocardial signal, the analog means including;

a generator configured to output a voltage signal level as a function of the interval value; and

an integrating element to integrate the electrocardial signal with the generator signal.

27. A computer-readable media having computer-readable instructions thereon, which, when executed by a computer, cause the computer to execute a method for synthesizing a reference value for an electrocardial waveform, the method comprising:

identifying a triggering event within the electrocardial waveform;

sampling the electrocardial waveform during an interval of relative inactivity; and

referencing the electrocardial waveform to the sample;

wherein the triggering event includes a first and a second feature of the electrocardial waveform.

Claims 1-15 and 27-32 stand rejected under 35 U.S.C. § 102(b) as anticipated by Nearing (US Patent No. 6,169,919 B1, Jan. 2, 2001) (Ans. 3).

Claims 16-26 stand rejected under 35 U.S.C. § 103(a) as obvious over Nearing in view of Ekstrom (US Patent No. 3,868,567, Feb. 25, 1975) (Ans. 5).

ANTICIPATION

The Examiner finds that "Nearing discloses referencing an electrocardial waveform, identifying a trigger, waiting for a period of isoelectric activity, sampling the wave, and dynamically referencing the voltage over a period of the selected beat that can utilize a computerized system" (Ans. 3). In particular, the Examiner finds that "Nearing discloses sampling an electrocardial waveform during a period of relative inactivity ('isoelectric') that corresponds to a specific beat and creating a spline curve. Nearing then references the electrocardial waveform to the sampled value over a period of a selected beat." (*Id.* at 6.) In addition, the Examiner finds that "Nearing further discloses that this is done in real-time" (*id.*).

Issues

Has Appellant shown that the Examiner erred in concluding that Nearing discloses: (a) "dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat," as recited in claim 1; (b) "a referencing element that applies the reference value to the voltage signal over a period of the selected beat," as recited in

claim 10; and (c) "referencing the electrocardial waveform to the sample" and a "triggering event includ[ing] a first and a second feature of the electrocardial waveform," as recited in claim 27?

Findings of Fact

1. Nearing discloses "a system and method for calculating a magnitude of alternation in the T-waves of an electrocardiogram [ECG] signal" (Nearing, col. 1, ll. 21-23).

2. Nearing discloses that preferably "a digitized ECG signal (i.e., ECG data) is received for processing" (Nearing, col. 1, ll. 51-52).

3. Nearing also discloses filtering the digitized ECG data (*id.* at col. 4, ll. 51-53, & Figs. 3-4).

4. In particular, Nearing discloses "applying a baseline wander removal filter to the ECG data to remove low frequency artifacts" (*id.* at col. 1, ll. 59-62).

5. Nearing discloses:

> The step of applying a baseline wander removal filter to the ECG data includes determining an isoelectric value at each of a first isoelectric point (point 1) in a first beat, a second isoelectric point (point 2) in a second beat, and a third isoelectric point (point 3) in a third beat of the ECG data; fitting a spline curve to the first three isoelectric values; [and] subtracting the values of the spline curve from the corresponding values of the ECG data.

(*Id.* at col. 1, l. 66, to col. 2, l. 6.)

6. In discussing the baseline wander removal filter (step 504), Nearing discloses that "the R-wave is generally used as a reference for locating other portions of the beat complex because its large amplitude permits it to be easily identified" (*id.* at col. 5, ll. 11-40).

7. Nearing also discloses that its method "may be implemented using hardware, software or a combination thereof and may be implemented in one or more computer systems or other processing systems" (*id.* at col. 9, ll. 14-17).

Analysis

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

With regard to claim 1, Appellant contends that "Nearing does not disclose dynamic referencing of a voltage value over a period of a beat. [Instead,] Nearing '...subtracts values of the spline curve from the corresponding values of the ECG data...' at multiple points in a beat of the waveform." (App. Br. 5.) We agree.

Claim 1 is directed to a method for applying a reference value to an electrocardial waveform including a series of heart beats. The method comprises "sampling the electrocardial waveform during [an] interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat." We interpret claim 1 to require that the waveform be referenced to the sample voltage value over the period of an entire heart beat.

Nearing discloses "subtracting the values of the spline curve from the corresponding values of the ECG data" (Finding of Fact (FF) 5). Nearing does not disclose applying the isoelectric value to the ECG data over a period of an entire heart beat. Instead, over the period of a heart beat,

Nearing references the waveform to spline curve values. Thus, we agree with Appellant that the Examiner has not set forth a prima facie case that Nearing discloses "referencing the electrocardial waveform to the sample voltage value over a period of the selected beat," as recited in claim 1.

With regard to claim 10, Appellant argues that Nearing "'...subtracts values of the spline curve from the corresponding values of the ECG data...' at multiple points over a beat. This is different than applying a reference voltage over a period of a beat." (App. Br. 5-6.) We agree.

Claim 10 is directed to a system comprising "a sampling device that determines [a] reference value corresponding to a selected beat; . . . and a referencing element that applies the reference value to the voltage signal over a period of the selected beat." As discussed above, Nearing discloses "subtracting the values of the spline curve from the corresponding values of the ECG data" (FF 5). Nearing does not disclose applying the isoelectric value to the ECG data over a period of an entire beat. Thus, we agree with Appellant that the Examiner has not set forth a prima facie case that Nearing discloses "a referencing element that applies the reference value to the voltage signal over a period of the selected beat," as recited in claim 10.

With regard to claim 27, Appellant argues that "the triggers cited by the Examiner in Nearing refer to step 508 of Nearing's method having to do with eliminating noisy beats from the ECG data (see Fig. 5) and not to Nearing's method of removing noise from beats" (Reply Br. 7). We are not persuaded. In discussing the baseline wander removal filter (step 504) for removing noise from ECG data, Nearing discloses that "the R-wave is generally used as a reference for locating other portions of the beat complex" (FF 4 & 6).

Appellant also argues that "Nearing does not disclose the use of first and second features as triggering events. Nearing only uses the apex of the R-wave as a determining reference." (App. Br. 6.) We are not persuaded.

As indicated by the Examiner, "claim 27 does not require multiple triggers. . . . [T]he claim does not state that the first and second features are used to trigger anything, just that the triggering event has a first and second feature." (Ans. 7-8.) In addition, we agree with the Examiner that, when the triggering event is an R-wave, it inherently contains first and second features (*id.* at 8).

In addition, Appellant argues "Nearing does not reference the waveform to the sample data directly" (Reply Br. 7). We are not persuaded. Although we agree with Appellant that Nearing does not disclose referencing a waveform to the sample voltage value over the period of an entire heart beat, we do not agree that Nearing does not directly reference the waveform to the sample data at the isoelectric points.

Conclusion

The Examiner has not set forth a prima facie case that Nearing discloses: (a) "dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat," as recited in claim 1; or (b) "a referencing element that applies the reference value to the voltage signal over a period of the selected beat," as recited in claim 10. We therefore reverse the anticipation rejection of claims 1 and 10 and of claims 2-9 and 11-15, which depend from claim 1 or claim 10.

However, Appellant has not shown that the Examiner erred in concluding that Nearing discloses "referencing the electrocardial waveform to the sample" or "a triggering event includ[ing] a first and a second feature

of the electrocardial waveform," as recited in claim 27. We therefore affirm the anticipation rejection of claim 27. Claims 28-32 fall with claim 27.

OBVIOUSNESS

The Examiner relies on Nearing as discussed above and for disclosing a digital system (Ans. 5). The Examiner relies on Ekstrom for disclosing "a method and apparatus for analysis of an isoelectric value in an electrocardial waveform, which includes a clock (48), analog sampler (52), amplifier/generator (44) and a peak detector/trigger (42)" (*id.*). The Examiner finds that the "system of Ekstrom samples an electrocardial waveform, finds an isoelectric sample within the waveform for a reference voltage, subtracts the reference voltage from the waveform using an amplifier, and outputs the final waveform" (*id.*). In particular, the Examiner finds that "Ekstrom teaches that it is known to use analog circuitry to detect and measure an[] isoelectric area of a electrocardial signal" (*id.* at 5-6). The Examiner concludes that it would have been obvious "to modify the digital system for referencing electrocardial waveforms as taught by Nearing, with [an] analog system as taught by Ekstrom" (*id.* at 6).

Issues

Has Appellant shown that the Examiner erred in concluding that it would have been obvious to include, in the alternation quantification system disclosed in Nearing, "a reference voltage generator for generating a voltage applied to the incoming signal substantially equal to the determined voltage value," as recited in claim 16; or an analog means including "a generator configured to output a voltage signal level as a function of the interval value; and an integrating element to integrate the electrocardial signal with the generator signal," as recited in claim 22?

Findings of Fact

8. As depicted in Figure 2, Ekstrom discloses "a prior system for obtaining the average ST segment depression," the ST segment being a relatively uniform segment between the S and T waves of an electrocardiagram waveform (EKG) (Ekstrom, col. 3, l. 44, to col. 4, l. 17).

9. In this system:

> An analog signal representing the EKG waveform is received from appropriate electrodes attached to the patient's body. This signal is provided as an input to the prior art circuit at terminal 10. The signal then passes through a variable signal delay 12 to a subtractor 14. An undelayed version of the signal is also provided to the subtractor via line 16 and to a trigger generator via line 18. By appropriately selecting the amount of signal delay 12, the subtractor 14 will subtract the PQ segment of the EKG signal from the ST segment to obtain the ST depression level. The resulting signal is displayed or subject to further processing as indicated by block 20.

(*Id.* at col. 4, ll. 17-29.)

10. As depicted in Figure 3, Ekstrom also discloses an ST analyzer that "eliminates the need for a variable signal delay and the superposition of EKG segments" (*id.* at col. 4, ll. 35-45).

11. In this system, an "analog EKG signal from a patient is received at terminal 30 and amplified by preamplifier 32" (*id.* at col. 4, ll. 44-47). The "analog EKG signal is then delta modulated by modulator 34 yielding a digital representation of such analog signal shown as a binary bit stream 38," which is further processed (*id.* at col. 5, ll. 1-38).

12. Ekstrom also discloses sources of voltage (*id.* at col. 9, l. 25, to col. 11, l. 49).

Analysis

Under 35 U.S.C. § 103, "the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

Nearing discloses "a system and method for calculating a magnitude of alternation in the T-waves of an electrocardiogram [ECG] signal" (FF 1). In particular, Nearing discloses "applying a baseline wander removal filter to the ECG data to remove low frequency artifacts" (FF 4). The method comprises

> determining an isoelectric value at each of a first isoelectric point (point 1) in a first beat, a second isoelectric point (point 2) in a second beat, and a third isoelectric point (point 3) in a third beat of the ECG data; fitting a spline curve to the first three isoelectric values; [and] subtracting the values of the spline curve from the corresponding values of the ECG data.

(FF 5.) Nearing also discloses that preferably "a digitized ECG signal (i.e., ECG data) is received for processing" (FF 2).

Ekstrom discloses an analog system for processing electrocardiogram data (FF 8). The method comprises subtracting analog signals (FF 9). We agree with the Examiner that it would have been obvious to modify Nearing's system to subtract analog, rather than digital, signals. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v.*

Teleflex Inc., *supra*. In order to utilize an analog subtractor in Nearing's digital system, it would have been obvious to include a voltage generator to generate a voltage substantially equal to the determined voltage value (i.e., the isoelectric value), so that this voltage could be subtracted from the incoming voltage signal.

Appellant argues, however, that "[n]either Nearing nor Ekstrom (nor any combination thereof) disclose analog components for generating a voltage" (App. Br. 9). We are not persuaded. Ekstrom discloses sources of voltage (FF 12). Thus, we agree that Ekstrom teaches or suggests analog components for generating a voltage. In fact, Appellant acknowledges that Ekstrom discloses an "analog circuit capable of creating a reference voltage" (Reply Br. 8).

Appellant also argues that "[n]either Nearing nor Ekstrom (nor any combination thereof) disclose applying a voltage to an incoming signal" (App. Br. 9). We are not persuaded. Instead, we agree with the Examiner that Ekstrom discloses applying a voltage to an incoming signal using a subtractor (FF 9).

In addition, Appellant argues that "[b]oth Nearing and Ekstrom manipulate digital ECG signals and not analog ECG voltage signals" (App. Br. 10). In particular, Appellant argues that "Ekstrom digitizes the ECG signal 'as a binary bit stream' as an initial step" and "Nearing states that 'in a first step a digitized signal is received for processing'" (*id.*).

We are not persuaded. Ekstrom does disclose a system in which an analog EKG signal is delta modulated "yielding a digital representation of such analog signal shown as a binary bit stream" (FF 11). However,

Ekstrom also discloses a prior art analog system (FF 8-9). The Examiner relies on Ekstrom for teaching this analog system (Ans. 8).

Appellant also argues that the "Examiner has failed to provide a sufficient suggestion or motivation in the prior art to combine or modify the reference teachings so as to arrive at the claimed invention. While both Nearing and Ekstrom analyze signal characteristics, they use different digitizing techniques; different analysis hardware and they have diverging objectives." (App. Br. 10.) In particular, Appellant argues:

> Ekstrom utilizes binary logic devices including flip flop circuits and bilateral switches in analyzing a binary bit stream representation of the ECG signal to determine a delta value. Nearing is converting the ECG signal to integer values and analyzing and comparing alternating waveforms with software algorithms. The circuit components of Ekstrom are configured to operate on a binary bit stream and will not function with the integer base digitization used by Nearing.

(*Id.* at 10-11.)

In addition, Appellant argues that "Ekstrom uses bit processing components to derive a difference value between two isoelectric points within a beat," whereas "Nearing uses software algorithms to develop complexes for an even series of beats and an odd series of beats" (*id.* at 11-12). Thus, Appellant argues that the "objectives of Ekstrom and Nearing are clearly distinct and divergent" (*id.* at 12).

We are not persuaded. As noted by the Examiner, he is relying on Ekstrom for disclosing a prior art analog system (Ans. 8). Thus, he is not combining Ekstrom's binary logic devices with Nearing's system. In addition, although Ekstrom is directed to determining ST depression whereas Nearing is directed to calculating T-wave alternation magnitude,

both references relate to processing electrocardiograms (FF 1 & 8). Thus, we do not agree that these references are so different that one of ordinary skill in the art would not have had reason to combine them.

Appellant also argues that "Nearing's reference value is not a direct voltage value of the received signal during an interval of relative inactivity. Instead, Nearing's reference value is a spline curve with many approximated values. . . . Therefore, Nearing . . . fails to disclose the claimed subject matter . . . having to do with determining the reference value." (Reply Br. 8.) In addition, Appellant argues:

> Even if Ekstrom's analog circuit capable of creating a reference voltage were somehow combinable with Nearing, the reference voltage created by the combination would be different than the Appellant's reference voltage, at least in part, because Nearing's reference value is determined differently than that of the Appellant and is a normalization approximation utilizing a spline curve instead of a directly obtained sample voltage value.

(*Id.*)

We are not persuaded. As discussed above, we do not agree that Nearing does not reference the waveform to the sample data at the isoelectric points. Thus, we conclude that it would have been obvious to include, in Nearing's system, a voltage generator that generates voltage as a function of the isoelectric values.

Conclusion

Appellant has not shown that the Examiner erred in concluding that that it would have been obvious to include, in the alternation quantification system disclosed in Nearing, "a reference voltage generator for generating a voltage applied to the incoming signal substantially equal to the determined voltage value," as recited in claim 16; or an analog means including "a

generator configured to output a voltage signal level as a function of the interval value; and an integrating element to integrate the electrocardial signal with the generator signal," as recited in claim 22. We therefore affirm the obviousness rejection of claims 16 and 22. Claims 17-21 and 23-26 fall with claims 16 and 22.

ORDER

We affirm the anticipation rejection of claims 27-32 and the obviousness rejection of claims 16-26. However, we reverse the anticipation rejection of claims 1-15.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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